UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS.	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

PLAINTIFFS' OPPOSITION TO DEFENDANT ASTRAZENECA PHARMACEUTICAL LP'S MOTION IN LIMINE TO EXCLUDE EVIDENCE RELATING TO GUILTY PLEAS AND SAMPLING ACTIVITY

In the Spring of this year, Plaintiffs and AstraZeneca briefed Plaintiffs' Motion for Partial Summary Judgment On Behalf of Classes 1 and 2 Against Defendant AstraZeneca Based on Its Guilty Plea Related to Zoladex [Dkt. No. 2272]. Apparently emboldened by this Court's comment at the May 23, 2006 hearing on that Motion that AstraZeneca's guilty plea might not "resolve[] one of the claims" (*see* Transcript of May 23, 2006 hearing, at 67), AstraZeneca now asks this Court to find ***as a matter of law*** that its plea, the guilty pleas of doctors who received AZ's samples, and AstraZeneca's entire sampling practice generally, are irrelevant. But nothing this Court has ever said nor the Federal Rules of Evidence support entering such a bar. Indeed, because AstraZeneca's sampling activity was one of the many ways that AstraZeneca sought to lower the acquisition costs of physicians and thus increase the spread, the Court should not exclude evidence regarding that practice at trial.

Specifically, AstraZeneca claims that this evidence is irrelevant because (1) Plaintiffs have not and cannot (because they do not have standing) allege claims under the Prescription Drug Marketing Act ("PDMA"); (2) the conduct underlying the plea has no factual relationship

to Plaintiffs' claims; (3) there is no connection between AstraZeneca's conduct and the class representatives; and (4) with regard to the doctors' pleas, they are not relevant because TAP is not a defendant in this trial. AstraZeneca therefore claims that admitting this evidence would "constitute a waste of this Court's time." AstraZeneca's attempt to escape the consequences of its criminal and fraudulent conduct should not be tolerated; its Motion in Limine should be denied.

I. ASTRAZENECA'S GUILTY PLEA

On June 20, 2003, AstraZeneca agreed to waive indictment and plead guilty to a one-count information charging it with conspiring to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 353(c), 331(t) and 333(b)(c)(B) ("PDMA"). *See* Memorandum of Plea Agreement, Ex. 1 to Schmeckpeper Decl. Specifically, the Information to which AstraZeneca pled guilty states, in part, as follows:

> 6. Beginning in or about 1993 and continuing to at least July, 1996, the defendant, Zeneca, through its employees, provided a total of thousands of free samples of Zoladex to physicians knowing and expecting that certain of those physicians would prescribe and administer drug samples to their patients and thereafter seek and receive reimbursement for those free samples.

During the plea and sentencing hearing before the Honorable Judge Joseph J. Farnan, Jr. in the District of Delaware, AstraZeneca agreed to plead guilty based on, among other things, the following proffer of conduct:

> PROSECUTOR: "Beginning in or about 1993 and continuing to at least July 1996, Zeneca here, through its employees, provided thousands of free samples of Zoladex to physicians knowing and expecting that certain of those physicians would prescribe and administer those drug samples to their patients and thereafter seek and receive reimbursement for the free samples.
>
> The objective for Zeneca was to obtain money from the increased sales of Zoladex, while the objective for the physicians was to obtain money for reimbursement for the samples of Zoladex.

> Therefore, it was an objective of Zeneca in this.... conspiracy to provide free samples of Zoladex to induce the urologists to order Zoladex.
>
> THE COURT: "...Do you agree with the government's proffer?"
>
> MR. ENGELMANN:[1] "Yes."
>
> THE COURT: "And that was the conduct of AstraZeneca, or the defendant?"
>
> MR. ENGELMANN: "Yes, it was, Your Honor."

See Declaration of Jennifer Fountain Connolly ("Connolly Decl."), Ex. A (Transcript of Hearing dated June 20, 2003, at 9-10).

The court also asked AstraZeneca, through Mr. Engelmann, if there was any dispute regarding whether "every essential element of the offense charged has been met by the evidence, both by your own admission and by the government's proffer[.]" Mr. Engelmann responded: "'No, I don't dispute that." *Id.* at 15. Based on that and other responses to questions posed by the court during the hearing, Judge Farnan accepted and entered AstraZeneca's guilty plea. *Id.* at 15-16. The Court thereafter sentenced AstraZeneca to one year of probation, a "special condition" of which required AstraZeneca to comply with the terms of the civil settlement agreement and pay $291,027,844 to the federal government and participating state Medicaid programs, as well as a criminal fine of $63,872,156. *Id.* at 17, 19.

II. PHYSICIANS' GUILTY PLEAS

AstraZeneca's admission is supported by the admissions of several doctors who stated that they billed for free samples and that AstraZeneca knew about that practice and promoted it.

[1] Mr. Engelmann is Glenn Engelmann, AstraZeneca's Vice President, General Counsel and Compliance Officer. Guilty Plea, at 7.

Three doctors[2] waived indictment and entered guilty pleas as co-conspirators, along with AstraZeneca.

As just an example, Dr. Robert A. Berkman waived indictment for and pled guilty to a one-count Information charging him with conspiring with AstraZeneca to violate the PDMA. *See* Berkman Information, Ex. 9 to Schmeckpeper Decl. At the plea hearing for Dr. Berkman, the government explained that:

> ...beginning in or around February 1994 and continuing at least until July 1996, Astra-Zeneca sales representatives provided to Dr. Berkman approximately 223 free one-month sample doses of Zoladex. Each sample was labeled not for retail sale and Dr. Berkman signed a sample receipt card for each sample dose he received. At least one Astra-Zeneca sales representative additionally provided Dr. Berkman's office with labels that Dr. Berkman's staff used to cover up the not-for-resale statement on the packaging. Dr. Berkman administered the free samples and received approximately $84,448 in billing for free samples.

See Connolly Decl., Ex. B (Transcript of July 17, 2003 Berkman Hearing at 10). Indeed, Drs. Antoun, Berkman and Hopkins alone, the doctors whose pleas AstraZeneca seeks to exclude, billed more than $200,000 for Zoladex free samples. *See* Antoun Plea Agreement ¶ 5 (Ex. 2 to Schmeckpeper Decl.) (stipulating that he received between $30,000 and $70,000 from billing free Zoladex® doses); Berkman Plea Agreement ¶ 5 (Ex. 3 to Schmeckpeper Decl.) (stipulating that he received more than $84,448.06); Hopkins Plea Agreement ¶ 4 (Ex. 4 to Schmeckpeper Decl.) (stipulating that he received approximately $69,900 from billing for the free Zoladex samples that he received).

[2] They are: (1) Saad Antoun, M.D., who practiced in Holmdel, New Jersey; (2) Robert A. Berkman, M.D., who practiced in Columbus, Ohio; and (3) Stanley C. Hopkins, M.D., who practiced in Boynton Beach, Florida.

III. THE PLEA-RELATED DOCUMENTS ARE RELEVANT BECAUSE ASTRAZENECA'S SAMPLING PRACTICES EXISTED PURSUANT TO COMPANY POLICY TO MARKET ZOLADEX'S RETURN TO PRACTICE

AstraZeneca claims that the plea-related documents Plaintiffs seek to use are not relevant to their claims. AZ's claim is false. According to Federal Rule of Evidence 401: "[r]elevant evidence means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."[3]

Based on this standard, the plea-related documents should be admitted at trial. As Judge Farnan, who presided over both the AstraZeneca and the defendant physician proceedings in the District of Delaware, noted at Dr. Berkman's sentencing hearing:

> I've told the other doctors [who appeared before this court in connection with similar offenses] that in my view, the perpetrator here was the drug company and the sales representatives. I told the last doctor who was here if he felt he was being treat [sic] unjustly, his feeling is correct he was being treated unjustly.

See Connolly Decl., Ex. C (Sentencing Hearing Tr. of Dr. Berkman (Nov. 6, 2003), at 7); and Ex. D (Feb. 5, 2004 Letter from Judge Farnan, Jr., to State Medical Board of Ohio on behalf of Dr. Berkman).

Judge Farnan's belief is confirmed by AstraZeneca's documents and witnesses in this case. While AstraZeneca's Motion in Limine leads this Court to believe that the only significance of AstraZeneca's sampling practice was that it violated the PDMA, AstraZeneca's sampling practices existed pursuant to company policy to market the spread for Zoladex. *See*, *e.g.*, Connolly Decl., Ex. E (Memorandum dated November 3, 1995 from Market Strategy &

[3] AstraZeneca likewise claims that TAP's plea documents are irrelevant but, because Lupron competed with Zoladex, and that competition led to the conduct of both companies that resulted in their guilty pleas, those documents are relevant here.

Contract Operations and the Zoladex Marketing Team (AZ0237142-163 at AZ0237143) (recommending increases to the published AWP for Zoladex and stating: "ZENECA has learned that in order to compete in [the] market dominated by Medicare, there needs to be a compelling argument based on "total return to practice." It is on this basis that many Urologists decide which LhRh agonist to use. *** Return to practice is derived by adding the difference between Medicare reimbursement [based on AWP] and acquisition price, ... patient co-pay which equals the 20% deductible that Medicare does not pay, and the benefit of [certain discounts].").

Indeed, AstraZeneca's own documents and testimony show that it viewed its sampling practices and marketing the spread as intertwined. As demonstrated below, the OIG Investigation and guilty plea were equated by AstraZeneca employees with the notion that selling the spread was illegal. Sales representative Matthew Metcalf, for example, testified that AstraZeneca instructed him and other sales representatives to avoid discussing Return to Practice directly with customers because of the OIG Investigation. Connolly Decl, Ex. F (Metcalf Dep. at 21-23). Erik Schultz, AstraZeneca's former Pricing Strategist, testified that the brand team response in the face of the OIG Investigation was to "lay low" on discussions of spread in order to avoid attracting OIG attention. Connolly Decl, Ex. G (Schultz Dep. at 91-95). *See also* Connolly Decl., Ex. H (CMS Account Team Kickoff Meeting (Feb. 10, 2003) at AZ0491336) (CMS and LEGAL ISSUES, Lessons from OIG – Things to Avoid, Discussions and analysis involving: Price Setting – AWP, Marketing the AWP spread, Return to Practice").

In short, when AstraZeneca provided Zoladex samples the acquisition price to the physicians for those samples was zero, making the total spread between that zero acquisition cost and the AWP at which physicians were billing, substantial. It makes no difference whether AstraZeneca "sold" Zoladex for $0 or for a wildly discounted price under its buy group

contracts. Plaintiffs will show at trial that that "selling" was all done pursuant to AstraZeneca's policy to market the spread. The conduct of selling profit to physicians via the spread by abuse and manipulation of AWPs and the Medicare reimbursement formula is the conduct of which Plaintiffs are complaining. That is the conduct to which AstraZeneca pled guilty, plain and simple.[4]

IV. ASTRAZENECA'S SAMPLING PRACTICES AFFECTED BOTH CLASS 2 AND CLASS 3 AND AFFECTED CLASS MEMBERS IN MASSACHUSETTS

In response to Plaintiffs' motion for partial summary judgment based on its guilty plea, AstraZeneca claimed that this Court could not grant partial summary judgment in Plaintiffs' favor because AstraZeneca's sampling activities purportedly had no effect on Class 1 representatives Mr. Townsend and Mr. Howe. *See* AstraZeneca Pharmaceutical LP's Memorandum Of Law In Opposition To Plaintiffs' Motion For Partial Summary Judgment On Behalf Of Classes 1 And 2 Against Defendant AstraZeneca Based On Its Guilty Plea Related To Zoladex [Dkt. No. 2387], at 5-6. Apparently according to AstraZeneca its conduct was a victimless crime that had no effect on anyone, for it argues in its motion in limine that there was also no connection between its sampling practices and the members of Class 2 or Class 3 because none of its sampling conduct occurred in Massachusetts. However, even though AZ seeks to exclude ***all*** evidence of its sampling activity, it asks this Court to do so by only considering the samples sold to the three doctors who pled guilty under the PDMA. But AstraZeneca did not

[4] AstraZeneca likewise makes the argument, as it did at the May 23 summary judgment hearing, that because Plaintiffs' expert did not include ***free*** samples in his damages theory, Plaintiffs cannot offer evidence regarding them at trial. Dr. Hartman did not include free samples in his damages analysis because, especially with regard to AstraZeneca, where there are facts in the record supporting that AstraZeneca representatives deliberately concealed that the free samples it was providing were, indeed, samples (*see* Connolly Decl., Ex. I (Berkman Tr. at 31:5-6); Ex. J (Antoun Tr. at 35:9-22); Ex. B (Transcript of July 17, 2003 Berkman Hearing, at 10), Dr. Hartman could not have included them in his analysis. But there is no question that Dr. Hartman's analysis includes the practice of lowering acquisition cost to increase the spread.

plead guilty to selling samples to only three doctors. (If it did one wonders about the attorneys who advised it to pay $350 million to resolve the charges against it.) AstraZeneca simply cannot draw a small circle around the conduct to which three doctors pled guilty and then ask this Court to preclude evidence of all ***its*** sampling activities, whether covered by the doctors' pleas or not.

AZ also claims that "[t]here is no evidence that any of the class members reimbursed a provider for a sample or made a co-payment for a sample." Defs. Mem. at 6. This argument, of course, ignores that providers who sought reimbursement for samples of Zoladex provided by AstraZeneca were told by AstraZeneca sales representatives that they were not, in fact, samples. *See* Connolly Decl., Ex. I (Berkman Tr. at 31:5-6); Ex. J (Antoun Tr. at 35:9-22). *See also* Connolly Decl., Ex. B (Transcript of July 17, 2003 Berkman Hearing, at 10) ("At least one Astra-Zeneca sales representative additionally provided Dr. Berkman's office with labels that Dr. Berkman's staff used to cover up the not-for-resale statement on the packaging. Dr. Berkman administered the free samples and received approximately $84,448 in billing for free samples."). There is no way based on AZ's conduct that a Class 2 or Class 3 TPP would know whether it had reimbursed for a sample.

Finally, AstraZeneca claims that the pleas of Drs. Antoun, Hopkins, Berkman are not relevant because none of those physicians practiced medicine in Massachusetts. But this Court did not restrict this trial to conduct that occurred in Massachusetts; it restricted it to ***injury*** that occurred in Massachusetts. For that reason, it is not relevant where those physicians practiced medicine. It only matters if there were TPPs or consumers who were affected by AstraZeneca's sampling conduct. And because its sampling conduct was part of AZ's policy to market the spread for Zoladex, it affected all members of Class 2 and Class 3.

V. ALLOWING PLAINTIFFS TO INTRODUCE EVIDENCE REGARDING ASTRAZENECA'S SAMPLING CONDUCT AND GUILTY PLEA WILL NOT BE "A WASTE OF THE COURT'S TIME"

Because of its relevance to the conduct challenged in this case, evidence regarding AstraZeneca's sampling conduct and guilty plea will not be, as AZ claims, a "waste of the Court's time."[5] AstraZeneca claims that its guilty plea will be an "unnecessary distraction," but this is not a jury trial. There is no danger that this Court, which has meticulously managed this litigation for five years, will be "distracted" by the introduction of this evidence.

AZ claims that if this evidence is admitted that this Court will have to hear and review evidence regarding, among other things, "the lack of any connection between the pricing of Zoladex and sampling activities, the limited scope of the sampling activity at issue in the various pleas," and other arguments – not evidence – that AZ has already made in its motion in limine. AstraZeneca simply ignores that its plea – and the scope thereof – speaks for itself. *United States v. Alegria*, 192 F.3d 179, 185 (1st Cir. 1999) (an unambiguous plea agreement should be enforced according to its tenor and an inquiring court should construe the written document within its four corners, and not consider covenants the parties did not see fit to mention), *see also United States v. De-La-Cruz Castro*, 299 F.3d 5, 14 (1st Cir. 2002). Further, there should be no evidence at trial regarding the scope of AZ's plea because AZ is collaterally estopped from relitigating the plea it and cannot, under the doctrine of judicial estoppel, take a position inconsistent with it in this litigation. *See DeCosta v. Viacom Int'l., Inc.*, 981 F.2d 602, 605 (1st Cir. 1992) (collateral estoppel); *Patriot Cinemas v. General Cinema Corp.*, 834 F.2d 208, 212 (1st Cir. 1987) (judicial estoppel).

[5] Defendants cite three cases for the proposition that evidence related to "tangential" issues should be excluded; however, the evidence sought to be admitted in those cases was either wholly irrelevant to the issues before the court, would have caused considerable delay, or could potentially confuse a ***jury***. *See Stathos v. Bowden*, 728 F.2d 15 (1st Cir. 1984); *Elgabri v. Lekas*, 964 F.2d 1255 (1st Cir. 1992); *United States v. Beauchamp*, 986 F.2d 1 (1st Cir. 1993).

Finally, AZ attempts to belittle the conduct that led it to plead guilty and pay over $350 million by claiming that "Dr. Berkman's plea only reference [*sic*] 641 total Zoladex samples that were billed." Not only does AZ's statement sadly belittle the conduct to which it pled guilty, but it also belied by the enormous fine it paid, the broad release granted by the government, and the extensive Corporate Integrity Agreement ("CIA") that followed the criminal action.[6] AstraZeneca paid a fine for its sample-related activities of $63,872,156 (based on an actual loss to the government of $39,920,098 with a 1.6 multiplier). *See* Memorandum of Plea Agreement ¶ 1a, Ex. 1 to Schmeckpeper Decl. Nonetheless, AstraZeneca agreed to pay an ***additional*** $291,027,844 to the United States and to the various state Medicaid programs that must account for some other injury resulting from AstraZeneca's criminal activities. *See id*. Thus, while AstraZeneca compromised with the government by pleading guilty to criminal fraud by PDMA violations, its payment to the government clearly was beyond the damages resulting from "certain" sampling by "certain" sales representatives. Furthermore, in consideration for AstraZeneca's plea, the government agreed to stop from "***further*** prosecut[ing]" AstraZeneca for "conduct falling within the scope of the grand jury investigation conducted by the United States Attorney's Office for the District of Delaware with respect to … the marketing, sale, and pricing of Zoladex in all its dose forms…." *Id.*, at ¶ 4b (emphasis added). Therefore, the guilty plea itself shows that it incorporated and accounted for more than "certain" free samples given by "certain" employees.

Following the guilty plea, AstraZeneca entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services ("OIG"). *See*

[6] Even if AstraZeneca were correct that its sampling activity only "marginally" affected the market for Zoladex, that would go to the weight of the sampling evidence, not its admissibility, and therefore would not provide grounds to exclude the evidence outright. *United States v Bear Killer*, 534 F.2d 1253, 1261 (8th Cir. 1976) (matters tending to reduce or enhance apparent probative value of evidence affect only weight of such evidence and not its admissibility.)

Connolly Decl., Ex. K. As part of the CIA, AstraZeneca was obligated to implement many training and monitoring programs going well beyond the issue of free samples. These programs include:

> [T]he calculation and reporting of accurate prices for Government Reimbursed Products to certain entities, including the Centers for Medicare & Medicaid Services ("CMS"), the State Medicaid programs, and the drug price reporting services on which government agencies now rely (i.e., First DataBank Inc., the Red Book, etc.) or shall rely in the future;
>
> [M]easures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to Government Reimbursed Products. The Policies and Procedures shall specify that AstraZeneca shall comply with the Federal antikickback statute, codified at 42 U.S.C. §§ 1320a-7b(I) & (2), and other applicable statutes, regulations or requirements.

See id. §§ III.B.2 (d) and (e). AstraZeneca's efforts to minimize the scope of its fraud to a few samples given by "certain of Zeneca's employees [to] certain urologists" grossly and improperly understates the implications of its illegal actions in order to evade liability to members of Classes 1 and 2.

WHEREFORE Plaintiffs respectfully request that this Court DENY Defendant AstraZeneca Pharmaceutical LP's Motion in Limine To Exclude Evidence Relating to Guilty Pleas and Sampling Activity, and all other relief that this Court deems just and proper.

DATED: October 16, 2006

By: /s/ Steve W. Berman

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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on October 16, 2006, I caused copies of **PLAINTIFFS' OPPOSITION TO DEFENDANT ASTRAZENECA PHARMACEUTICAL LP'S MOTION IN LIMINE TO EXCLUDE EVIDENCE RELATING TO GUILTY PLEAS AND SAMPLING ACTIVITY** to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman
Steve W. Berman